

to demonstrate reduction to practice of the invention, at least commensurate with the extent the invention is shown in the cited art (see below), a demonstration of diligence, as suggested by the Examiner, is not believed to be required.

The Section 103 rejection of claims 1-12 over Kreindel (U.S. Patent No. 6,162,212) in view of Amornsiripanitch (U.S. Patent No. 6,389,150, referred to hereinafter as "Amor" as suggested by the Examiner) is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing comments.

The presently claimed invention provides a system for simulation and predictive analysis of the evolution of a hair region of the dermis of a subject over time. The claimed system requires:

(1) a means for observation of the hair region able to output digital observation data;

(2) a first digital data processing means capable of classifying the hairs of the hair region observed by the means of (1) based on the observation data and external data;

(3) a second digital data processing means capable of simulating the evolution of the hairs as a function of the data emanating from the first digital data processing means – the data emanating from the first digital data processing means having been obtained from the hair region observed by the means of (1); and

(4) a means of displaying the data emanating from the second digital data processing means. The data output by the first data processing means of the claimed system includes at least one classification according to the diameter of the hairs.

The "system" of Kreindel, as exemplified in Figure 4 of the patent, only provides means for collecting information regarding (a) the gender of the patient (i.e., item (14) of Figure 4), (b) the hair location (i.e., item (16) of Figure 4 ("Arms, Axillae, Cheeks, Chin, Legs, Pubic Area, Upper Lip")), and (c) the efficiency of the device used for performing the hair removal treatment. See, column 4, lines 39-41. The "system" of Kreindel, again as illustrated by Figure 4 of the patent, provides an output of (i) information about hair growth cycle (i.e., item (18) of Figure 4) and (ii) duration of the growth stage (i.e., item (20) of Figure 4). See, column 6, lines 42-43 of Kreindel.

Kreindel does not teach or suggest a system including a means for observation of hair region of the dermis, as required by the presently claimed invention. As further described below, the secondary reference fails to cure this deficiency.

Specifically, the Examiner is urged to appreciate that Kreindel describes calculation of (i) information about hair growth cycle and (ii) duration of the growth stage, from

"data available from previous published studies about the relative number of hair in the Anagen stage for different gender and different areas of the body"

which was considered "reliable". See, column 3, lines 44-52 of Kreindel. "This data can be determined from histology analysis of hair follicles." Id.

Kreindel is understood to describe the statistical calculation of the hair growth cycle as a function of gender and area of the body by comparing an equation which represents a statistical calculation of the hair growth cycle for each area of the body based on empirical data of clearance after the first laser hair removal and regrowth rate

for different body sites, with a calculation of the hair growth cycle. See, column 3, line 39 through column 4, line 65.

The hair growth cycle for each area is not based on a specific individual's characteristics or based on observations of a hair region of a specific individual. As recognized by the Examiner, the characteristics used by Kreindel to analyze the hair growth cycle and duration of the growth cycle is not based on diameter of the hairs of the individual being analyzed, or even on the diameter of the hairs from previous published studies. See, page 5, penultimate and final line, of Office Action dated September 9, 2004.

The Examiner's assertion that Kreindel

"discloses to observe the hair growth cycles on a patient and to simulate the growth of hair over time (Kreindel et al.; Col. 3, lines 37-41 and 53-67 and Col. 6, lines 36-49)" (see, page 5 of the Office Action dated September 9, 2004)

is not correct. The noted passages of Kreindel state the following:

received information about the gender of the person to be treated and an area on said person's skin to be treated. Furthermore, in another embodiment of the present invention, the hair removal treatment is simulated by showing the hair growth cycle and the effect of a light pulse on ...

Other objects and advantages of the invention will become apparent upon reading the following detailed description and appended claims, and upon reference to the accompanying drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The present invention is described with reference to the accompanying drawings, wherein like reference numerals or characters indicate corresponding or like components. In the drawings:

FIG. 1 is a schematic illustration of the hair growth during the Anagen stage;

FIG. 2 is a schematic illustration of the treatment efficiency as a function of time during the Anagen stage; ....

On the main screen 10, a graphic illustration 12 is shown, which describes randomly the approximate ratio between hair in the Anagen stage (dotted lines) and hair in the Telogen stage (lines). After entering parameters concerning the gender of the patient (14), the hair location (16) and the efficiency of the device used for performing the treatment (not shown), information about hair growth cycle (18) and duration of each growth stage (20) is provided, and the graphic illustration changes accordingly. Further, optimal delays between sessions and number of sessions, 22 and 24 accordingly, are suggested. By clicking the button referenced 26, the dynamic of hair growth can be observed. Each pressing on this button simulates by using the graphic illustration 12 hair regrowth one week ahead. A session of...

As detailed above, neither these passages nor the whole of Kreindel describe or disclose or suggest "to observe the hair growth cycles on a patient" as asserted by the Examiner. Rather, Kreindel is understood to teach a relatively simple system to calculate "information about hair growth cycle" and "duration of the growth stage" based on the gender of a patient and the hair location. Curiously enough, Kreindel states "This process is not functional if information about the duration of the hair growth cycle and the Anagen stage of the treated person is provided." See, column 3, lines 41-43 of Kreindel.

The Examiner admits that "Kreindel does not teach a first processing nor second processing", as required by the present claimed. However, the Examiner further asserts that

"It is a matter of configuration of obtaining a final product. One skilled in the art may make one processor which may obtain the final product or design the system where 2 or more processors may perform specific tasks to obtain the

same final product." See, page 5 of the Office Action dated September 9, 2004.

While it may be true, in the abstract of the Examiner's comments, to perform functions with multiple processors, the Examiner has not indicated or identified where the art would have suggested the data processing of the presently claimed system. Specifically, the Examiner has not indicated where the cited art teaches or suggests a system which includes even a single digital processing means which combines the functions of the first digital processing means (capable of classifying the hairs of a hair region of the dermis of a subject, based on observation data from an observation means and external data) and second digital processing means (capable of simulating the evolution of hairs as a function of the data emanating from the first digital processing means) of the presently claimed system.

The Examiner admits that Kreindel does not disclose

"to classify according to the diameter to the diameter of the hairs." See, page 5 of the Office Action dated September 23, 2004.

The Examiner relies on Amor to assert that

"It would have been obvious to one skilled in the art to combine the teachings of Amor [i.e., in allegedly teaching to classify the growth of the hairs according to the diameter of the hairs] to .....Kreindel....because they are analogous in analyzing the growth of hairs and obtaining certain parameters pertaining to the growth cycles of the hairs. One skilled in the art would have been motivated to incorporate the teaching, classifying the growth cycles according to the diameter of the hair shafts, of Amor to the system of Kreindel et al in order to observe and record the dynamic changes of all the parameters throughout the hair's life cycle (Amor; Col. 2, lines 24-26)." See, pages 5-6 of the Office Action of September 9, 2004.

The Examiner only relies on Amor to allegedly teach a classification by hair diameter. Even if there were a motivation in the art to combine the cited references, which there was not, Amor would not cure the above-noted further deficiencies of Kreindel.

Initially, the applicants question whether Kreindel and Amor are "analogous" art, as suggested by the Examiner. Kreindel was classified by the U.S. PTO in the following Classes/Subclasses: 606/9; 606/131, while Amor was classified in the following Classes/Subclasses 382/100; 382/128. The Examiners of the respective applications/patents did not search art in overlapping Classes/Subclasses.

Moreover, as noted above, Kreindel does not teach a method of "analyzing" the growth of hairs and/or "obtaining certain parameters" pertaining to the growth cycles of hairs, as stated by the Examiner. Rather, Kreindel teaches a method of using available published data to statistically determine information about hair growth cycle and duration of the growth stage based on the gender of a patient, the hair location (as selected from a general list of body locations), and the efficiency of the laser device used to eliminate hair.

One of ordinary skilled in the art would not have been motivated to incorporate the teaching of Amor ("classifying the growth cycles according to the diameter of hair shafts")

"to the system of Kreindel.... in order to observe and record the dynamic changes of all parameters throughout the hair's life cycle"

because Kreindel is interested in eliminating hair with a laser device. That is, if Kreindel's method of hair removal is successful, then there will be no "dynamic

changes....[of any] hair's life cycle" to observe or record. If Kreindel is successful, there will be no hair after the first treatment with the laser hair removal device. Moreover, as noted above, Kreindel is only interested in information about the hair growth cycle and duration of the growth stage.

Kreindel is interested in this limited information regarding hair growth as these results apparently allow an estimation of the optimal delay between laser hair removal treatments and the optimal number of laser hair removal treatment sessions. See, Figure 4 "Statistics" of Kreindel.

One of ordinary skill would not have been motivated to combine the teachings of Amor to Kreindel in the manner suggested by the Examiner.

Claim 1, and claims 2-12, are submitted to be patentable over Kreindel in view of Amor.

For completeness, the following comments are provided in response to the Examiner's remarks on pages 6-10 of the Office Action dated September 9, 2004.

With regard to claim 2, the applicants believe that Kreindel, at best, is using published literature results relating to the relative number of hairs in the Anagen stage for different genders and different areas of the body. See, column 3, lines 46-51 of Kreindel. Kreindel has not taught or suggested a system containing a means of observing the hair region of the dermis of a subject which is able to output digital observation data or a first digital data processing means capable of classifying the hairs of the region on the basis of the observation data. Moreover, Kreindel fails to teach or suggest classification by a first digital data processing means according to the diameter

of the hairs and/or according to whether the hairs belong to the Telogen, Anagen or Disappeared phases. Amor fails to cure these deficiencies.

With regard to claim 3, the applicants agree with the Examiner that Kreindel provides output information based on gender of a subject. See, page 6 of the Office Action dated September 9, 2004 and column 6, line 40 of Kreindel. The applicants may tend to also agree with the Examiner that

"Many factors are important in studying the results of an experiment such as gender, age, eating habits, drugs presently taking, etc." Id.

Kreindel however does not teach or suggest the classification of hairs of a region based on digital observation data and the age of the subject, as required by the presently claimed system. Kreindel does not teach or suggest that it is, or even that it may be, important to study the results of age, eating habits and/or drugs presently taking, in order to determine information about hair growth cycle and duration of the growth stage in an attempt to predict the optimal delay between laser hair removal treatments and the optimal number of laser hair removal sessions. The only information about the subject to be treated which is required by Kreindel is the gender of the patient and the location of the hair, as selected from a broadly described list of available options. There are no means in Kreindel's system for using information about a person's age, eating habits and/or drugs presently taking and to provide or include the same in the system of Kreindel would be contrary to Kreindel. Amor fails to cure these deficiencies.

Regarding the Examiner's comments relating to the alleged obviousness of the system of claim 4, the applicants again note that the cited art fails to teach or suggest



the system of claim 1, from which claim 4 depends. Moreover, Table 1 of Kreindel is understood to provide a statistical determination of duration of Anagen phase and calculated average growth cycle based on "reliable" data available from previously published studies of, apparently, 645 patients, Kreindel does not teach or suggest a system containing a second processing means capable of calculating the proportion A of hairs in the Anagen phase based on classification of hairs from a first digital data processing means which was, in turn, based on digital observation data of a hair region of the dermis of a subject. Amor fails to cure this deficiency.

With regard to the Examiner's comments relating to claim 5, the applicants again note that the cited art fails to teach or suggest the system of claim 1, from which claim 5 depends. Moreover, Kreindel does not teach or suggest a system capable of calculating and forecasting the surface density of hairs, the proportion T of hairs in the Telogen phase, the proportion D of Disappeared hairs and/or the individual rate of growth of the hairs. Rather, Kreindel teaches a system which, at best, provides "statistics" about the growth cycle, growing period, optimal delay in laser hair removal treatments and optimal number of laser hair removal sessions. The

"approximate ratio between hair in the Anagen stage (dotted lines) and hair in the Telogen stage (lines)"

displayed on the preferred embodiment of Kreindel (Figure 4 of the patent) is a "random" description (see, column 6, lines 36-39 of Kreindel) which is apparently not affected by the input parameters relating to a specific patient. Id. Moreover, the calculation of hair growth cycle from previously published studies which is taught by Kreindel appears to mathematically eliminate the number of follicles in the Telogen

stage ( $N_t$ ) and the Telogen stage duration ( $t_t$ ) by expressing these values as function of the number of follicles in the Anagen stage ( $N_a$ ) and the Anagen stage duration ( $t_a$ ), respectively. See, columns 3-4 of Kreindel. In this manner, Kreindel is understood to ignore the proportion of Disappeared hairs – contrary to the system of claim 5 of the presently claimed invention. As noted above, the only disappeared hairs which concern Kreindel are those removed by a laser hair removal process. See, column 4, lines 31-34 of Kreindel ("hair clearance after the first session of the hair removal treatment"). Amor fails to cure these deficiencies. Reliance on any additional "parameters" taught by Amor in the method or system of Kreindel would have been contrary to the specific mathematical calculations of Kreindel.

The Examiner's comments with regard to claim 6 are noted. It would have been contrary to the system of Kreindel to simulate the evolution of the entire head of hair of a subject as Kreindel does not teach or suggest laser hair removal of an entire head of hair, which is the purpose of Kreindel's calculations. Moreover, the previously published studies used by Kreindel only relate to specific locations of the Chin, Upper lip, Axillae, Bikini, Legs and Arms. See, Table 1 of Kreindel, which only provides information relating to females. There is no teaching or suggestion in Kreindel (or Amor) to simulate the evolution of the entire head of hair of the subject. For completeness, the applicants again note that the cited art fails to teach or suggest the system of claim 1, from which claim 6 depends.

With regard to the Examiner's comments relating to claim 7, the applicants again note that the cited art fails to teach or suggest the system of claim 1, from which claim 7 indirectly depends. The system of claim 7 is patentable over the cited art.

The Examiner's comments with regard to claim 8, which are the same as those discussed above with regard to claim 1, have been addressed above. The following further distinctions are also provided with regard to claim 8.

The process of Kreindel does not involve observation of a hair region of the scalp of a subject to provide digital observation data. The method of Kreindel provides, at best, a laser treatment location indicator selected from Arms, Axillae, Cheeks, Chin, Legs, Pubic Area, and Upper Lip. See, Figure 4 of Kreindel. Kreindel does not teach or suggest a process involving the scalp or specifically obtaining or processing digital observation data relating to the scalp. Amor fails to cure these deficiencies. Claim 8 is patentable over the cited art.

The Examiner's comments regarding claim 9 are noted. The applicants submit that the cited art fails to teach or suggest the process of claim 8, from which claim 9 depends. More importantly perhaps, it would have been contrary to the overall process of Kreindel (or Amor) to shave prior to the laser hair removal process of Kreindel, to the extent the hair removal process is considered a part of the overall process of Kreindel's teaching, as patients of laser hair removal processes presumably subject themselves to laser hair removal so that they do not need to shave. To the extent the laser hair removal process of Kreindel is not considered a part of the overall process of Kreindel, there is no data, observation or otherwise, from the subject being treated which relates to hair removal or requires prior hair removal, for any calculation of Kreindel.

With regard to claims 10 and 11, applicants submit that the cited art fails to teach or suggest the process of claim 8, from which claim 10 and claim 11, depend. With regard to claim 12, the Examiner is requested to see the entirety of the above.


LOUSSOUARN et al.  
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The claims are submitted to be patentable over the cited art and a Notice of Allowance is requested.

Respectfully submitted,

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